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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,207	05/13/1999	NIGEL DUNN-COLEMAN	GC369-2PCT	5860

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/308,207

Applicant(s)

DUNN-COLEMAN ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 32-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Reasons for allowable subject matter.

The request filed on Nov. 23, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/308207 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1-40 are pending in the application. Claims 1-31 are the subject of this Office Action. Claims 32-40 are withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to the non-elected invention.

Detailed Office Action

1.1. Objections

1.1. Abstract

The abstract is missing. For examination purposes the abstract of the PCT publication WO 98/21341 was used. This abstract is objected to because it does not describe the invention as now claimed. It is silent about usage of **dehydratase activity** in combination with proteins X and protein 1, protein, 2 or protein 3. In addition, the source and function of protein X, protein 1, protein 2, and protein 3 are not quoted. A new abstract is required. See MPEP § 608.01(b).

1.2. Drawings

This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Figure 9 and 10 are objected because description of coordinate y is missing.

1.3. Disclosure

The disclosure is objected to because the symbol ® in equations 1, 2, 3, 4, on pages 1 and 2 has no meaning, and should be replaced by an arrow. Appropriate correction is required. *wd*

The specification is objected for the definition of protein X. On page 10, line 34, Applicants write, "The phrase 'protein X of a dehydratase gene cluster' or 'dhaB protein X' or 'protein X' refers to a protein that is comparable to protein X of the *Klebsiella pneumoniae* dehydratase gene cluster as shown in Figure 2 or alternatively comparable to protein X of *Klebsiella pneumoniae* diol dehydratase gene cluster as shown in Figure 8. Preferably protein X is capable of increasing the production of 1,3-propanediol in a host organism over the production of 1,3-propanediol in the absence of protein X in the host organism. Being comparable means that DNA encoding the protein is either in the same structural location as DNA encoding *Klebsiella* protein X with respect to *Klebsiella* dhaB1, dhaB2 and DhaB3, i.e., DNA encoding protein X is 3' to nucleic acid encoding dhaB1-B3, or that protein X has overall amino acid similarity to either *Klebsiella* diol or glycerol dehydratase protein X. The present invention encompasses protein X molecules having at

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least *K. pneumoniae* glycerol or diol dehydratase or the *C. freundii* protein X."

This description of protein X is indefinite and confusing. The phrase "protein X capable of increasing the production of 1,3-propanediol in a host organism over the production of 1,3-propanediol in the absence of protein X in the host organism" is not identifying, as many proteins, for example the glycerol phosphatase, have that capability.

The phrase "Being comparable means that DNA encoding the protein is either in the same structural location as DNA encoding *Klebsiella* protein X with respect to *Klebsiella* dhaB1, dhaB2 and DhaB3, i.e., DNA encoding protein X is 3' to nucleic acid encoding dhaB1-B3." is confusing because on page 11 line 27 Applicants write, "the present invention encompasses a method for enhanced production of 1.3-propanediol wherein the gene encoding protein X is transformed in a host cell together with genes encoding the dehydratase activity and/or other genes necessary for the production of 1.3-propanediol. The gene encoding protein X, dehydratase activity and/or other genes may be on the same or different expression cassettes." It is therefore obvious for the one skilled in the art that the protein having the role of protein X in the claimed invention does not need to be encoded by a DNA "in the same structural location as DNA

encoding Klebsiella protein X with respect to Klebsiella dhaB1, dhaB2 and dhaB3."

The description of protein X as "protein X has overall amino acid similarity to either Klebsiella diol or glycerol dehydratase protein X" is indefinite, because proteins having only one amino acid changed may lose their functions and even very high percentage of identity does not assure the same function; see Seffernick J. et al. (Melamine Deaminase and Anthrazine chlorohydrolase: 98 percent identical but functionally different, J. Bact. 2001, 183, 2405-2410).

The address of the American Type Culture Collection on page 9, line 34 is wrong.

1.4. Claims

Claim 6 and 24 are objected to because the word Citrobacter contains a spelling error.

2. Rejections

2.1. 35 U.S.C. section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 2, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention. The phrases "protein X", "protein 1", "protein 2" and "protein 3" in claims 1, 2, 19, and 20 render the claims indefinite. The claims do not recite the function and structure of said proteins, thus, do not set forth the metes and bounds of the patent protection desired. Claims 3 and 8-14 and 21-23 are included in this rejection because they are dependent from rejected claim 1 or 2 or 19-20 and do not correct deficiency of the claims from which they depend.

Claim 15 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the nucleic acid sequence encoding protein X, wherein the sequence has the sequence identification number SEQ ID NO: 59. This renders the claims indefinite, because SEQ ID NO: 59 is not a nucleotide sequence but amino acid sequence. The specification fails to disclose the nucleotide sequence encoding any of protein X.

2.3. *Statutory double patenting*

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 3, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18 are rejected under 35 U.S.C. 101 as claiming the same invention as, respectively, that of claims 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 of prior U.S. Patent No. 6,136,576. This is a double patenting rejection.

2.4. Nonstatutory double patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).


A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1, 4, 5, 6 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,136,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of claim 1, 4, 5, 6 and 7 encompass the method

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for production of 1,3-propanediol that is recited in claim 1 of the patent. Thus, the combine scope of claim 1, 4, 5, 6, and 7 of the instant application is the same as the scope of claim 1 of the patent.

Claims 2, 16, 17 and 18 of the instant application are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,136,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 2, 16, 17 and 18 of the instant application encompass the method for production of 1,3-propanediol that is recited in claim 2 of the patent. 

3. Allowable subject matter

Claims 19-31 would be allowable if claims 19 and 20, 22 and 23 were rewritten or amended to overcome the rejection under 35 U.S. C. 112 set forth in this office action.

The following is a statement of reasons for the indication of allowable subject matter: there is no prior art of record teaching a recombinant microorganism capable of producing 1,3-propanediol from a carbon source said recombinant microorganism comprising a gene encoding dehydratase activity, a gene encoding glycerol-3-phosphatase and a gene encoding protein X. There is also no teaching about said recombinant microorganism containing additionally protein 1, protein 2 or protein 3.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.


If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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Assistant Patent Examiner



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